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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,593	06/27/2001	F. Mark Ferguson	SHP025.1	4461
7590	03/17/2004		EXAMINER	
Mark S. Leonardo, Esq. Brown Rudnick Berlack Israels LLP One Financial Center Boston, MA 02111			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 03/17/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/892,593	FERGUSON ET AL.	
<b>Examiner</b>	<b>Art Unit</b>		
Catherine S. Williams	3763		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-9, 11, 14-90 and 93 is/are pending in the application.
- 4a) Of the above claim(s) 21, 22, 24, 26, 32-59, 61, 66-68, 73-90 and 93 is/are withdrawn from consideration.
- 5) Claim(s) 1-4 and 71 is/are allowed.
- 6) Claim(s) 5, 6, 11, 14, 15, 19, 25, 30, 31, 62-64, 69, 70 and 72 is/are rejected.
- 7) Claim(s) 7-9, 16-18, 20, 23, 27-29, 60 and 65 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

DETAILED ACTION

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 69 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Gyure et al (US Pat# 5,665,075). Gyure discloses a needle shield assembly that includes a needle hub (28) and a shield (45). See figure 2. The needle hub has a collar (34) that receives the proximal end of the shield (43). The shield has a lock (58) that captures a portion of the needle disposed proximal to the distal end of the needle. See figure 4. The shield encloses at least a portion of the distal end of the needle. See figures 3 and 4. The shield also includes at least one hinge (see figures 1-4) that has a relief (83). The hinge flexes inwardly. See figure 1.

Claims 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Orgain (US Pat# 5,188,611). Orgain discloses a safety sheath for needles that includes a needle hub (23) and a shield (21). See figures 16-23. The shield includes a lock (44) that captures a portion of the needle disposed proximal to the distal end of the needle. See figures 18 and 20. The shield also encloses at least a portion of the distal end of the needle. See figures 17 and 19. The shield also includes a locking means (78) for locking the shield in the extended position. See figure 16.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6, 11, 14, 19, 25, 30-31 and 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gyure et al (US Pat# 5,665,075). Gyure discloses a needle shield assembly that includes a needle hub (28) with an open ended needle and a shield (45). See figure 2. The needle hub has a monolithically formed collar (34) that receives the proximal end of the shield (43). The collar also has an interior cavity. See figure 2. The shield has a lock (58) that flexibly and irreversibly captures (locks) a portion of the needle disposed proximal to the distal end of the needle when in the extended position. See figures 4 and 10. The shield encloses at least a portion of the distal end of the needle. See figures 3 and 4. The proximal end of the shield (41) is received by the collar (34) of the needle hub in interlocking engagement. See figures 2 and 7. As shown in figure 2, the needle hub has a luer fitting (29) for attaching to a syringe. The needle hub includes guide surfaces (flange 33) to facilitate engagement of the shield and needle hub. The shield has a proximal segment and at least one rib (69) with a transverse orientation for urging the shield to the extended position. See figure 4.

Gyure meets the claim limitations as described above but fails to include the proximal end of the needle shield being received within the cavity of the needle hub collar. However, Gyure does teach a proximal end of a needle shield being received by (surrounding) a collar of a needle hub. See above.

At the time of the invention, it would have been obvious to rearrange the parts of the proximal end of the needle shield and the collar of Gyure so that the proximal end of the shield is received into the collar of the needle hub. The courts have found the rearrangement of parts unpatentable if the rearrangement does not modify the operation of the device (In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)) and an obvious matter of design choice (In re Kuhle, 526 F.2d 553, 188 USPQ7 (CCPA 1975)). Rearranging the Gyure reference to have the proximal end of the needle shield locking into the cavity of the collar would not modify the overall operation of the device (i.e.) shielding the needle. Additionally, applicant has not disclosed that having the proximal end of the shield locking into the cavity of the collar provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the proximal end of the needle shield locking into engagement with the outside of the collar as taught by Gyure. Therefore, it would have been an obvious matter of design choice to modify Gyure to obtain the invention as specified in claim 5-6, 11, 14, 19, 25, 30-31 and 62-63.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gyure in view of Orgain. Gyure meets the claim limitations as described above for claim 5 but fails to include the shield having locking means for locking the shield in the extended position. However, Orgain discloses locking means on the shield for both locking the shield to the hub and locking the shield to the needle. See above description of Orgain.

Since Gyure already discloses locking means on the shield for locking the shield to the needle, it would have been obvious to incorporate the additional locking means on the shield and

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have a redundant locking system as taught by Orgain. The motivation for the incorporation would have been in order to enhance the safety of the device to the user by having two locks to prevent a needle stick.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gyure. Gyure meets the claim limitations as described above for claim 5 but fails to include a double wall needle.

At the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a double wall needle because applicant has not disclosed that using a double wall needle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a regular hypodermic needle. Therefore, it would have been an obvious matter of design choice to modify Gyure to obtain the invention as specified in claim 64.

***Allowable Subject Matter***

Claims 1-4 and 71 are allowed.

Claims 7-9, 16-18, 20, 23, 27-29, 60 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*.  
March 6, 2004

*Brian L. Casler*  
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